Complete Summary

GUIDELINE TITLE

Nephrolithiasis.

BIBLIOGRAPHIC SOURCE(S)

Nephrolithiasis. Philadelphia (PA): Intracorp; 2005. Various p. [12 references]

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from July 1, 2005 to July 1, 2007.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, the U.S. Food and Drug Administration (FDA) asked manufacturers of non-prescription (over the counter [OTC]) non-steroidal anti-inflammatory drugs (NSAIDs) to revise their labeling to include more specific information about potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drugs. See the FDA Web site for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all NSAIDs make labeling changes to their products. FDA recommended proposed labeling for both the prescription and OTC NSAIDs and a medication guide for the entire class of prescription products. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Nephrolithiasis (renal calculi), including

- Calcium stones
- Struvite stones
- Uric acid stones
- Cystine stones

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nephrology
Surgery
Urology

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, management, and treatment of nephrolithiasis that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Individuals with suspected or known renal calculi

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Physical examination and assessment of signs and symptoms
2. Diagnostic tests
    - Urinalysis
    - 24-hour urine
    - Blood chemistries, including uric acid levels, blood urine nitrogen (BUN), and creatinine
    - Kidney, ureter, and bladder (KUB) x-ray
    - Intravenous urography
    - Intravenous pyelogram
    - Ultrasound

Management/Treatment

1. Medical management, including hydration, analgesia, strain urine, and medications, such as
    - Nonsteroidal anti-inflammatory drugs (NSAIDS)
    - Antibiotics
    - Diuretics
    - Citrates
    - Phosphates
    - Allopurinol
    - Penicillamine
    - Acetohydroxamic acid
2. Abdominal x-rays every 1 to 2 weeks
3. Referral to specialists
4. Surgical management, including
    - Stent placement
    - Cystoscopy or ureteroscopy
    - Percutaneous nephrolithotomy
    - Extracorporeal shock wave lithotripsy (ECSWL)

MAJOR OUTCOMES CONSIDERED

- Risk factors for renal calculi
- Sensitivity, specificity, and accuracy of diagnostic tests
- Effectiveness of treatment at eliminating stones

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Colic (severe intermittent flank pain)
    - Pain may radiate to groin, testicles, labia majora
- Nausea, vomiting
- Report of bloody urine
- History of chronic urinary tract infection (UTI)
- History of prior renal stones
- Dysuria (painful or difficult urination)
- Restless appearance

Objective Findings

- Costovertebral tenderness
- Deep abdominal tenderness
- No peritoneal irritation
- Usually afebrile unless coexisting infection
- Hematuria (red blood cells in urine)

Diagnostic Tests

- Urine analysis; results may show:
    - Microscopic or gross hematuria

    - Crystals in urine
    - Pyuria with coexisting infection
- 24-hour urine; for measurement of calcium, sodium, creatinine, uric acid, pH, and total volume
- Blood chemistries:
    - Uric acid levels
    - Blood urine nitrogen (BUN)
    - Creatinine
- A kidney, ureter, and bladder (KUB) x-ray; more than 90% of stones are radiopaque
- Intravenous urography (only if diagnosis is uncertain)
- Intravenous pyelogram (IVP); establishes the diagnosis of calculus disease in 96% of cases
- Ultrasound

Differential Diagnosis

- Aortic aneurysm dissection
- Urinary tract infection [UTI] (see the Intracorp guideline Urinary Tract Infection)
- Back strain (see the Intracorp guideline Low Back, Acute and Mild)
- Disc disease (see the Intracorp guideline Low Back, with Radiculopathy, Myelopathy)
- Passage of blood clots in ureters

Treatment

Treatment Options

- Stones less than 5 millimeters diameter pass spontaneously 90% of the time.
- Stones greater than 8 millimeters require urologic intervention.
- Medical management
    - Hydration
    - Analgesia
    - Strain urine
    - Medications:
        - Non-steroidal anti-inflammatory drugs (NSAIDS)
        - Antibiotics for UTI
        - Diuretics (thiazides)
        - Citrates (e.g., K-Lyte, Urocit-K)
        - Phosphates (e.g., K-phos, Calcibind)
        - Allopurinol (e.g., Lupurin, Zyloprim)
        - Penicillamine (e.g., Catopril)
        - Acetohydroxamic acid (e.g., Lithostat)
- Abdominal x-rays every 1 to 2 weeks
- If stone does not pass in 2 weeks, refer to urologist.
- May require hospital admission for uncontrolled nausea and vomiting
- Surgical management
    - Indications
        - Completely obstructed kidney
        - Solitary kidney with partial obstruction
        - Urine extravasation on IVP

        - Stone greater than 10 mm diameter
        - Nonpassable stone of any size
    - Options
        - Stent placement to temporize
        - Cystoscopy or ureteroscopy (see the Intracorp guideline Cystoscopy)
        - Percutaneous nephrostolithotomy
        - Extracorporeal shock wave lithotripsy (ECSWL) (see the Intracorp guideline Lithotripsy)

Duration of Medical Treatment

- Medical - Optimal: 7 day(s), Maximal: 90 day(s)
- Surgical - Optimal: 14 day(s), Maximal: 90 day(s)

Additional information regarding primary care visit schedules, referral options, and specialty care is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- Resolving pain, fever without hospitalization
- Resolving fever, hydration, obstruction with hospitalization
- After lithotripsy without complications
- After hospitalization for surgical intervention

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and management of nephrolithiasis that will assist medical management leaders to make appropriate benefit coverage determinations

POTENTIAL HARMS

Adverse Effects of Medications

- Some people cannot tolerate citrate salts because of digestive side effects.
- Side effects of acetohydroxamic acid (AHA) can be severe.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Urographic contrast medium is contraindicated in patients with renal insufficiency and prior reaction to contrast material.
- None of the citrates should be used by people with struvite stones, urinary tract infections, bleeding disorders, or kidney damage.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.
- Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 15, 2005. The information was verified by the guideline developer on September 30, 2005.

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